DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, Maryland 20850

93497d

SEP 10 2002

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Cees Akkerman, CEO
Movingpeople.net
Lage DIJK 10
5705 BZ Helmond, The Netherlands

Dear Mr. Akkerman:

We are writing to you because on May 28-30, 2002, an investigator from the Food and Drug Administration (FDA) collected information that revealed serious regulatory problems involving your Fortress Model 1700, 1704, 2000, and 2001 Power Scooters, and your Corsaire Power Chair, manufactured at your Movingpeople.net Canada, Inc., facility located at 500 Norfinch Drive, Toronto, Canada.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body (Section 201(h) of the Act).

The above stated inspection revealed that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation of these devices are not in conformance with the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. In legal terms, the products are adulterated within the meaning of section 501(h) of the Act, as follows:

1. **Failure to establish procedures for management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency to ensure that the quality system satisfies the requirements of 21 CFR Part 820 and the manufacturer's established quality policy and objectives, as required by 21 CFR 820.20(c).** For example, there are no written procedures for Management Review.

2. **Failure to establish procedures for quality audits and to conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the**

effectiveness of the quality system, as required by 21 CFR 820.22. For example:

a. There are no procedures for Internal Audits.

b. No Internal Audits of the quality system have been performed in the last year.

3. **Failure to establish procedures for identifying training needs and failure to ensure that all persons are trained to adequately perform their assigned responsibilities, as required by 21 CFR 820.25.** For example:

   a. There are no procedures for training.

   b. There is no documentation that any employee has been trained in the manufacturing operations.

4. **Failure to designate an individual(s) to review for adequacy and approve prior to issuance all documents that are required by this part, as required by 21 CFR 820.40(a).** For example, the following are two examples of SOPs that have not been approved:

   a. Procedure for Electric & Electronic Assemblies.

   b. Quality Assurance Form #104A Quality control 100% Final Inspection.

5. **Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50.** For example, there are no written Procedures for Purchasing Control.

6. **Failure to adequately establish and maintain procedures for acceptance of incoming product, as required by 21 CFR 820.80(b).** For example, incoming acceptance activities are not performed on incoming components and no Certificates of Analysis are received from vendors of components, for the Fortress Model 2000 and 1704 scooter devices.

7. **Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a).** For example, there are no written procedures for Corrective and Preventive Actions (CAPA).

8. **Failure to establish and maintain procedures for implementing corrective and preventive action for analyzing work operations, quality audit reports, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR 820.100(a)(1).** For example, there is no analysis of work operations, quality audit reports, and quality in-process and final acceptance activity records to identify existing and potential causes of nonconforming product.

9. **Failure to establish and maintain procedures for implementing corrective and preventive action for verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4).** For example, the following are instances where there is no documentation that changes made to the device were tested to determine that they were effective and did not adversely affect the device:

   a. ECN # 2823, dated 10/16/01 for any 4-wheeler, documents that a tie rod axle bracket was changed from a two-piece weld to a one-piece laser cut.

   b. ECN # 2824, dated 10/22/01 for the Model 2000 Scooter, documents the front frame tube was modified from a two-piece weld to a one-piece tube with an indent.

10. **Failure to establish and maintain procedures for implementing corrective and preventive action for submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review, as required by 21 CFR 820.100(a)(7).** For example:

    a. Relevant information on identified quality problems, as well as corrective and preventive actions, are not submitted for management review.

    b. No management review meetings were held in the last year.

    c. No management representative has been appointed.

    d. There are no written procedures for conducting management review.

11. **Failure to adequately establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a).** For example:

    a. There are no written procedures for complaint handling.

    b. There is no complaint handling unit.

12. **Failure to analyze service reports with appropriate statistical methodology and in accordance with 21 CFR 820. 100, as required by 21 CFR 820.200(b).** For example, between January - May 2002, and for all of 2001, no complaints have been recorded for the Fortress Models 2000 and 1704 Scooters. Over this same time period, however, service has been performed for device failures for approximately 275 Fortress Models 2000 and 1704 Scooters. Examples of documentation of such service reports not analyzed as complaints follow:

    a. Return Authorization A 032628, 1/28/02 for Model 1704, in which the charger did not work.

b. Return Authorization A 032534, 3/08/02 for Model 2000, in which the controller was defective.

c. Return Authorization A 032602, 2/05/02 for Model 2000, in which the LED on the console assembly was not working.

The law also requires under Section 519 of the Act that manufacturers and importers of devices establish and maintain such records, make such reports, and provide such information as the FDA by regulation reasonably requires to assure that a device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. The FDA issued the Medical Device Reporting Regulation, 21 CFR Part 803, under section 519. The investigation revealed that your firm has not met the requirements of 21 CFR Part 803 as follows:

Failure to develop, implement, and maintain, written MDR procedures, as required by 21 CFR 803.17.

Because your firm has not complied with the requirements of 21 CFR Part 803, your products are in violation of the law. In legal terms, the products are misbranded under Section 502(t)(2) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA.

If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Given the serious nature of these violations of the Act, the various model Fortress Power Scooters and the Corsaire Power Chair, manufactured by Movingpeople.net Canada, Inc., may be detained without physical examination upon entry into the United States until these violations are corrected.

In order to remove the devices from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that your response is adequate, we will request an establishment re-inspection at that time. As soon as the re-inspection has taken place, the implementation of your corrections has been verified, and you are notified that your corrections are adequate, your devices may resume entry into this country.

Please notify this office in writing of the specific steps you have taken to correct the noted violations. Include an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an

estimated date of completion, and documentation showing plans for correction should be included with your response to this letter. If the documentation is not in English, please provide an English translation to facilitate our review.

Please address your response to:

Christy L. Foreman, Chief
Orthopedic, Physical Medicine &
Anesthesiology Devices Branch
Office of Compliance
Division of Enforcement III (HFZ-343)
Center for Devices and Radiological Health
2098 Gaither Rd.
Rockville, MD 20850
USA

If you have any questions about the contents of this letter, please contact Mr. William Defibaugh at the above address or at (301) 594-4659, ext. 121, or fax (301) 594-4672. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers, International and Consumer Assistance (DSMICA, formerly DSMA) at (800) 638-2041, or through the Internet at http://www.fda.gov.

Sincerely yours,

for Philip J. Frappaolo
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

cc: Mr. Clarence M. Rivette
Managing Director
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